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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,199	10/17/2001	Gregory P. Pogue	42202	4164

27860 7590 07/15/2005

LARGE SCALE BIOLOGY CORPORATION
3333 VACA VALLEY PARKWAY
SUITE 1000
VACAVILLE, CA 95688

EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,199	Applicant(s) POGUE ET AL.	
	Examiner Georgia L. Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 33, 34, and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 33, 34, and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

1. The Office acknowledges receipt of Applicants Response of 26 April 2005.
2. Applicant has canceled claims 35-39, amended claims 5, 7, and 9, and added new claims 40-42. Claims 5-10, 33, 34, and 40-42 are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-second

6. Claims 5-10, 33, 34, and 40-42 are rejected under 35 U.S.C. 112-2nd because Applicant's amended language in claim 5, 3rd line, "infecting a plant by itself without another virus" remains ambiguous . Does the plant not have another virus? Or is Infecting "without another virus"?

Suggested language is to insert in line 2 "by itself" following "said virus is" and delete "by itself" in line 3. Equivalent changes need to be made to claims 7 and 9.

Claim Rejections - 35 USC § 112-1 written description.

7. Claims 5-10, 33, 34, and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record as set forth in Office Action of 26 January 2005 . Applicant gives a schematic diagram (Figure 3, and specification p. 9 lines 11-17) of the p0144-BoLys vector, saying that "regulatory

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elements known as subgenomic promoters are shown: SP-E transcribes the mRNA for.... SP-1 transcribes the mRNA encoding the Bolys protein. SP-2 transcribes the mRNA encoding the coat protein." However there is no sequence or size description of these regulatory elements. No recombinant RNA plant viruses, no RNA molecules comprising a first viral subgenomic promoter, a second viral subgenomic promoter, and a bovine lysozyme coding sequence under control of either the first or the second viral subgenomic promoter, and no recombinant tobamoviruses other than SEQ ID NO: 1-3 are described.

The specification does not disclose what biological or structural features would be present in the recombinant RNA plant viruses, the RNA molecules comprising a first viral subgenomic promoter, a second viral subgenomic promoter, and a bovine lysozyme coding sequence under control of either the first or the second viral subgenomic promoter, or the recombinant tobamoviruses which would be necessary for the function of these sequences and viruses in order for them to function in the claimed invention.

There is no structural description information, other than SEQ ID NO: 1-3, is given. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Applicant traverses saying primarily (p. 5) that numerous publications recite different RNA plant systems, given a list of US patents, and that all these publications are incorporated by reference and are themselves full descriptions should one be interested. Applicant's traversal is unpersuasive. The structural features which define the genus Applicant claims are not described.

Claim Rejections - 35 USC § 112

8. Claims 5-10, 33, 34, and 40-42 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record as set forth in the Office Action of 26 January 2005.

Applicant traverses saying (Response, p. 5-6) primarily that Applicant is not claiming the production of every gene with the plant vector system or RNA, only lysozyme. Saying further that "Applicants have experimentally established (after much effort) that this gene can be expressed in reasonable amounts with the recited vector system". Applicant further asserts that "given the large number of different recombinant virus vector systems using different recombinant viruses and different subgenomic promoters etc. have been used in the past to express various genes in plants by way of transient expression in the cytoplasm, Applicant's do not see any reason to question their use in the present invention" (p. 6, 3rd full ¶).

Applicant's traversal is unpersuasive. Accordingly to Applicant, "not all recombinant foreign genes are capable of being expressed by a RNA plant virus". (See Applicant's Response of 15 October 2003, p. 7-9.) Applicant set forth:

"[I]n order to infect and replicate an RNA virus in plants and for the foreign to be expressed many events must occur, some of which are not predictable.... These include: i) the recombinant virus with the lysozyme gene must be able to replicated in the plant cell, ii) the recombinant virus must retain the lysozyme sequence long enough to made the protein, iii) the specific recombinant construct must be compatible with the host plant cell, iv) to infect the whole plant the recombinant virus must be able to move through the growing parts of the plant while retaining the lysozyme gene , v) the virus capsid must be able to assemble and to encompass both the viral genome and the

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additional lysozyme gene, vi) the lysozyme gene must be expressed and not degraded by the plant cell, vii) the expressed lysozyme must be retained by the plant sufficiently to protect it from bacterial infections, and viii) unlike vectors containing a lysozyme gene, infectious viruses must retain all the other biological properties in order to infect that a whole plant.” In other words, Applicant documents of the unpredictability of the system. This is in accord with the present enablement rejection.

Claim Rejections - 35 USC § 103

9. Claims 5-10, 33, 34, and 40-42 are rejected under 35 U.S.C. 103(a) as being obvious over Mirkov, et. al. US # 5,850,025, issued 15 December 1998, in view of Donson, et. al., US # 5,316,931, issued 31 May 1994, for reasons of record and for reasons discussed in the Office Action mailed 26 January 2005.

Applicant traverses saying primarily that “a biologically active form of lysozyme has not been show by Mirkov et. al., who showed producing a biologically active lysozyme in yeast”. That Mirkov et. al. has not showed any enzymatic activity/biological activity for their plant-produced protein.

Applicant's traversal is unpersuasive. Mirkov et. al. clearly teach production of bovine lysozyme expressed in the plants (column 29, lines 37-40. The enzyme produced by Mirkov has the appropriate antigenic binding characteristics and size of the bovine lysozyme (Figure 5). The lysozyme thus produced maintains biological activity, as conferring reduced susceptibility of the plants to bacterial infection. Applicant has not

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defined biological activity to include only appropriate enzymatic activity. Therefore the appropriate antigenic binding characterizes and size qualify as biological activity.

Remarks

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

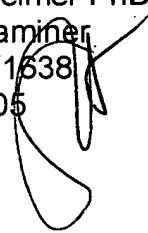
Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

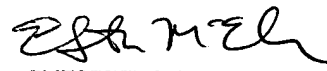
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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
July 7, 2005




ELIZABETH MCELWAIN
PRIMARY EXAMINER